

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

Project Title: Tucson AccuMed Replacement and Manual Filling Stations

1. **Contracting Activity:** Department of Veterans Affairs, National Acquisition Center (NAC), requests approval of this justification for other than full and open competition for the purchase and installation of fully automated Robotic dispensers and manual filling stations at the Tucson Consolidated Mail Outpatient Pharmacy (CMOP). The purchase request number for this requirement is: 762-13-1-819-0004.
2. **Nature and/or Description of the Action Being Processed:**
This request is to sole source this requirement to a small business for the purchase and installation of robotic dispensers and manual filling stations utilizing a firm-fixed price type contract. This requirement will be sole sourced to Innovation Associates.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:**
The Tucson CMOP is replacing all of its AccuMed automation and fully automating the majority of its manual filling areas. The current system has been in operation for approximately 6 years and processes approximately 2,500 prescriptions/day. The manufacturer will no longer support the current system with spare parts and maintenance service after September 2013. The new required automation shall provide fully automated dispensing, be integrated with existing conveyor lines, include software integration and be capable of producing a minimum of 9,000 prescriptions per 7.5 hour shift. A fully automated dispensing system contains the following features and follows the process as described below:
 - a robotic arm that retrieves the prescription bottle from the conveyor;
 - the robotic arm lifts the prescription bottle under the correct prescription chute;
 - the dispenser pre-counts the correct number of capsules or tablets;
 - the dispenser fills the prescription bottle; and
 - the robotic arm puts the filled prescription bottle back into the puck and restarts the steps again.

No human intervention is required to fill the prescription bottles under the fully automated dispensing system. Systems that are not fully automated require humans to manually retrieve empty bottles, scan the barcode, wait for the correct chute from the dispenser to fill, place the bottle under the chute, press the chute for filling, cap the bottles, and rescans the filled bottles to enter back into the puck.

A fully automated system is required to (i) fulfill more low volume line items, (ii) increase productivity, (iii) replace equipment that will no longer be supported after September 2013 (iv) reduce staffing levels, and (v) improve all safety aspects of dispensing by eliminating the potential for human error. The replacement will maintain the current footprint while increasing productivity by using a fully automated filling system. Paragraph 5 provides in depth detail regarding the requirement.

The estimated cost for new dispensers and manual filling stations is \$1,465,000.00. The estimated time for completion is six months from contract award date.

4. Statutory Authority Permitting Other than Full and Open Competition:

- (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- () (2) Unusual and Compelling Urgency per FAR 6.302-2;
- () (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- () (4) International Agreement per FAR 6.302-4
- () (5) Authorized or Required by Statute FAR 6.302-5;
- () (6) National Security per FAR 6.302-6;
- () (7) Public Interest per FAR 6.302-7;

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

a. Only One Responsible Source (FAR 6.302-1) In accordance with 41 U.S.C. 253(c)(1), Innovation Associates provides a highly specialized, uniquely designed fully automated pharmaceutical dispensing system which, based on market research, is currently unavailable from any other commercially available source.

As described in paragraph 3, the Tucson CMOP requires a fully automated system to (i) fulfill more low volume line items, (ii) increase productivity, (iii) replace equipment that will no longer be supported after September 2013, (iv) reduce staffing levels, and (v) improve all safety aspects of dispensing by eliminating the potential for human error.

(i) The Tucson CMOP is required to dispense more line items of the lower volume medications, which this system will allow. A fully automated system will allow more line items to be added while increasing throughput. A non-fully automated system will require increased human intervention and decreased throughput while increasing potential for errors. Innovations dispenser accurately counts transparent medications, such as vitamin E gel capsules, valproic acid gel capsules, benzonatate gel capsules and others, which is not provided by any other type of dispenser. These types of gel capsules currently are counted manually. Based on market research, no other systems are capable to accurately dispense transparent medications.

(ii) A fully automated system is required to increase productivity. Tucson CMOP's current dispensing stations produce a throughput of 2,500 prescriptions per day. The new robotic dispensers and manual filling stations will be increased to 9,000 prescriptions per day due to fully automated technology. The current system does not hold the capacity of required cells needed for fulfillment. Human intervention also decreases productivity because their speed to fill is based on each employee's capability. The new system counts transparent medications which are currently being performed by CMOP employees. This feature alone removes the potential for human error and increases throughput requirements. Equipment failures and replenishment requirements are also a significant delay in current throughput requirements. The new system being fully automated has greater technology advances to produce a higher throughput. Due to the requirement of increase in line items of the low volume items, the current system is required to be fully

automated.

(iii) Replace equipment that will no longer be supported after September 2013. The current system will need to be replaced immediately to fill veteran patient prescriptions without delay. The AccuMed system frequently breaks down and malfunctions. The manufacturer will no longer support the current AccuMed system with spare parts or maintenance service after September 2013. Tucson CMOP's production system fills orders based on FIFO (first in first out). Due to the FIFO order filling process, our production system will be waiting for the completion of the orders from the AccuMed system before the production system will drop any other orders. Therefore, if AccuMed Dispensers breaks down, within a few hours the entire main production line will come to a halt and no prescriptions will be able to be filled in the entire facility.

(iv) Reduce staffing levels. Full automation will reduce staff needed to fulfill the increase in line items of the low volume items. Semi-automated systems will require additional staff to fulfill the increase in line items of the low volume items. The difference between staffing from a fully automated vs. a semi-automated dispenser is significant. A fully automated system will require one technician per four dispensing stations for replenishment purposes only. The current semi-automated requires two dedicated employees per dispenser: one to fill prescriptions and one to replenish the canisters. Innovations dispenser accurately counts transparent medications, such as vitamin E gel capsules, valproic acid gel capsules, benzonatate gel capsules and others, which is not provided by any other type of dispenser. These types of gel capsules currently are counted manually. The other systems are not able to dispense these gel capsules. Innovations dispensers will allow Tucson CMOP to replace pharmacists/technicians and automate 6,500 more prescriptions per day that are currently manually filled

(v) Improve all safety aspects of dispensing by eliminating the potential for human error. A fully automated system will decrease the potential for human error. Human error occurs with the systems that are not fully automated with both the dispensing of product into the vials/pucks and replenishing the dispensers used for dispensing the product into the vials/pucks. The fully automated system will only dispense product into the correct vial/puck and has safety mechanisms in place to only allow one dispenser to be replenished at a time with a lock out feature that only unlocks once the correct barcode for that assigned product is scanned. After conducting thorough market research, it became apparent Innovation is the only company that can provide a fully automated dispenser.

The ease of care and maintenance keeps lifecycle costs at a minimum. The dispensers are self-calibrating and do not need cleaning. Therefore no supplies, such as cleaning tools and cleaning solutions need to be purchased. By utilizing this system, the Tucson CMOP will be able to dispense more line items in the same footprint. The dispensers contain flexibilities that allow the CMOP to upgrade both hardware and software as technology advances without the need to purchase new dispensers. The dispensers already possess the software interface capabilities for both QMSI and McKesson. Therefore, no additional cost will be required to interface the software with the current QMSI and McKesson contractors. Accordingly, Innovation is the only contractor capable of providing the products described in Section III above without the Department of Veterans Affairs experiencing unacceptable delays in fulfilling its requirements. The government would be detrimentally impacted due to unacceptable delays should the Contracting Officer try to compete this requirement knowing no other product exists in the commercial market.

In September 2012, Tucson CMOP was notified the Parata's AccuMed system will no longer be supported with parts or technical support effective September 2013. The Tucson CMOP does not maintain a spare parts inventory and is completely reliant on Parata's parts inventory and support for continued operations. This makes it critical that new equipment is procured and installed immediately to avoid

production failures which ultimately impact timely delivery of patient medications. Failure to procure new equipment in a timely manner has the potential to halt all prescription fulfillment processes at the Tucson CMOP thereby impacting mission performance and negatively affecting patients' lives.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

Based on market research, the Contracting Officer determined a total of six companies offered prescription dispensers. Three of those companies were found on GSA; another three responded to the sources sought notice posted on FedBizOpps and provided their product presentation. Further details are provided below.

The Contracting Officer reviewed the GSA schedule and determined three companies offered a prescription dispenser however; the Contracting Officer could not procure these items on GSA due to the dollar amount for open items not on the GSA schedule. For instance, the awardee's units shall be completely automated, interface with the existing software, include manual filling stations, and integrate with existing conveyors. All these requirements are not on the GSA schedule and will exceed the amount of \$3,000 allotted for open market items on GSA purchases.

A sources sought notice was posted to FBO on 2/7/2013. The synopsis number is VA797M-13-I-0124. The sources sought notice requested interested contractors to submit their response and capabilities no later than 2/22/2013. Respondents were invited to conduct teleconference with the Tucson CMOP customers to explain their company, products provided and any past performance information in relation to fully automated robotic dispensing cabinets. Three companies responded to the sources sought notice. All three companies provided a presentation to the Tucson CMOP customers. The companies were asked their units capabilities, counting accuracy, canister and chute capacity, integration solutions with current software, ease of maintenance and cleaning, and technical and maintenance support. Two of the three companies who responded to the sources sought notice did not meet the fully automated requirement per the sources sought notice. Only one company demonstrated they had the products and technology to meet Tucson CMOP's requirements which is Innovation Associates.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable: The Contracting Officer will determine fair and reasonable pricing by comparing the dispenser price with like items shown on GSAAAdvantage.gov. The Contracting Officer will conduct a price analysis to determine fair and reasonable pricing in accordance with FAR 6.303-2(a)(7).

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:

As described in Section 6 above, market research, in accordance with FAR Part 10, was conducted by synopsis of the proposed acquisition, advising industry of the pending acquisition and soliciting inquiries from interested parties.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition: A Statement of Work has been developed and incorporated into the solicitation. The dispensing units offered by Innovation Associated is highly specialized and uniquely designed to meet the requirements of the Tucson CMOP. This equipment is integrated into the main production line that produces 87% of the 45,000 prescriptions dispensed each day to our nations Veterans. Equipment failure anywhere on this main line has the potential to cease all prescription fulfillment operations. Failure would impact every Veteran residing in the states of

Arizona, Nevada, California, Hawaii, and Guam. Therefore, if any of the AccuMed Systems malfunction or breakdown, the Tucson CMOP prescription fulfillment throughput will be adversely affected. Replacement dispensers are needed immediately to provide patient medications in a timely manner to sustain life. (see FAR 6.302-1(b)(2) and 6.303-2(a)(9)(i)).

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition: See Section 6 above.

11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:

The Contracting Officer maintains open communication with customers and contractors to define the future needs of all CMOP's. The Contracting Officer provides contractors information of the CMOP's vision and where technology is advancing to in order to keep up with the increased prescription fill rates. The information provided to contractors allows them to review their current technology to build and improve upon to meet the future needs of the CMOP's. The Contracting Officer allows regular site visits to CMOP's and open communication with customers for continued learning experience. Eventually, new contractors will fully understand VA's future and create equipment to meet the needs for each CMOP.

12. Requirements Certification: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.



Anthony Felix – Associate Director
Tucson Consolidated Mail Outpatient Pharmacy

4/3/2013

Date

13. Approvals in accordance with FAR 6.304

a. Contracting Officer's Certification (required): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



Nonya Trower - Contracting Officer
National Acquisition Center

4/3/2013

Date

b. NAC Associate Director: I certify the justification meets requirements for other than full and open competition.




Frank Zacchigna – Associate Director
VA National Acquisition Center - CMOP

4/3/13

Date

- c. NCS Director: I certify the justification meets requirements for other than full and open competition.



Steve Thomas - Director
National Contract Service
VA National Acquisition Center

4/4/13

Date

- d. OGC Review and Approval: This justification and approval has been reviewed and has been found to be legally sufficient.

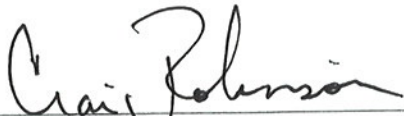


Vanessa Calabrese - Contract Attorney
VA National Acquisition Center

04/05/2013

Date

- e. HCA Review and Approval: I certify the justification meets requirements for other than full and open competition.



Craig Robinson
Head of Contracting Activity (HCA)
VA National Acquisition Center

04/12/13

Date